PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Duvyzat (givinostat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Duvyzat, initially approved by the FDA in 2024, is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.
DMD is an X-linked, progressive disease characterized by muscle wasting, weakness, loss of walking ability, and reduced life expectancy. It is caused by mutations in the dystrophin gene resulting in reduced or near absence of dystrophin, a protein that helps keep muscle cells intact.
Delaying loss of ambulation is a major goal of treatment. Corticosteroids are standard of care to improve muscle strength and function in DMD and may prolong walking ability. In a phase 3 trial, Duvyzat combined with steroids showed statistically significant less decline in the 4-stair climb when compared to placebo. Less worsening was seen on the North Star Ambulatory Assessment (NSAA) but it was not statistically significant.

Duvyzat (givinostat) will be considered for coverage when the following criteria are met:

Duchenne Muscular Dystrophy (DMD)

For **initial** authorization:
1. Member is male; AND
2. Member is at least 6 years of age; AND
3. Medication must be prescribed by or in consultation with a neurologist or neuromuscular specialist; AND
4. Member has a diagnosis of DMD confirmed by genetic testing that shows DMD gene loss-of-function variation, or absence of muscle dystrophin on muscle biopsy; AND
5. Member is ambulatory; AND
6. Chart notes document a baseline platelet count of greater than 150 x 10^9/L; AND
7. Member meets **BOTH** of the following:
   a) Member has been stable on a corticosteroid for at least 6 months prior to starting therapy with Duvyzat;
   b) Member will continue stable dose of corticosteroid while being treated with Duvyzat; AND
8. Member's weight is documented in chart notes.
9. **Dosage allowed/Quantity limit:** Administer orally twice daily with food per the table below. Quantity limit: 3 cartons per 30 days.

Weight	Dosage	Oral Suspension Volume
10 kg to less than 20 kg	22.2 mg twice daily	2.5 mL twice daily
20 kg to less than 40 kg	31 mg twice daily	3.5 mL twice daily
40 kg to less than 60 kg	44.3 mg twice daily	5 mL twice daily
60 kg or more	53.2 mg twice daily	6 mL twice daily

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show stability or slowed rate of decline of the member's motor function and muscle strength.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Duvyzat (givinostat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/29/2024	New policy for Duvyzat (givinostat) created.

References:

1. Duvyzat [package insert]. Italfarmaco S.A.; 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. *Lancet Neurol.* 2018;17(3):251-267. doi:10.1016/S1474-4422(18)30024-3.
3. Malaga M, Rodriguez-Calienes A, Chavez-Ecos FA, et al. Clinical practice guidelines for the diagnosis and management of Duchenne muscular dystrophy: a scoping review. *Front Neurol.* 2024;14:1260610. Published 2024 Jan 5. doi:10.3389/fneur.2023.1260610
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(5):465-472. doi:10.1212/WNL.0000000000002337
5. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2024;23(4):393-403. doi:10.1016/S1474-4422(24)00036-X

Effective date: 10/01/2024
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